

Application No. 10/659,063  
Filed: September 10, 2003  
TC Art Unit: 1623  
Confirmation No.: 3827

REMARKS

The pending claims have been finally rejected for indefiniteness and lack of enablement. These rejections are respectfully traversed for the reasons given below and reconsideration is requested.

The Applicants express their appreciation for the telephone interviews the Examiner conducted with their undersigned representative on July 22 and 29, 2005. An amendment was discussed that would address the enablement rejection. In addition, the Applicants' support in the specification for overcoming the indefiniteness rejection was also discussed. In the July 29<sup>th</sup> telephone interview, the Examiner informed the Applicants' representative that he was inclined to allow the claims if the amendment and the enhanced arguments were submitted in written form, which the Applicants' representative provides herewith.

Claim 1, which was rejected for lack of enablement, is amended herein, in the preamble thereof, as requested by the Examiner. Thus, the Applicants submit that the rejection has been overcome. The Applicants state for the record that they have made this amendment for the sole purpose of advancing the claims to

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allowance and continue to believe that the rejected claims are enabled by the specification, as previously argued.

Claims 1-6 and 8 have been rejected under 35 USC § 112, second paragraph. The Examiner states that the terms "a functional analogue or derivative" render the claims indefinite. The Applicants submit that the definiteness requirement has been met through the entirety of the teachings in the specification. In particular, the Examiner is referred to the section in the specification from p. 9, line 24 - p. 10, line 25. Here, for example, as cADPR can be considered substantially like a nucleotide but without its base portion, the Applicants have pointed to the extensive investigations carried out in recent years to identify oligonucleotide analogues as a method of making clear to those of ordinary skill the scope of the term "functional analogue or derivative" as applied to cADPR in the recitation of the claimed method. Specific citations are made in this section to the work in identifying nucleotide analogues that is relevant to those wishing to modify cADPR to practice the claimed method, and the specification teaches (see, sentence from p. 9, line 30 - p. 10, line 2) that appropriate derivatives are "mimetics that activate the same anti-inflammatory pathway(s)." To permit the determination as to whether or not a candidate "functional

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analogue or derivative" is a "mimetic[]" that activate[s] the same anti-inflammatory pathway(s)," the specification describes three assay systems, two *in vitro* systems (see, p. 7, line 31 - p. 9, line 5) and one *in vivo* system (see, p. 9, lines 6-23). Furthermore, starting at p. 10, line 26, specific methods of administration are described, and at p. 11, lines 7-10, a citation is given to exemplary methods for providing the compounds used in the method of the invention in drug form.

The Applicants submit that a combination of this level of identification of "analogues or derivatives," along with a definition of the "function" they are to carry out, in combination with three identified assays, one of which is *in vivo*, render the claimed invention definite to one of ordinary skill in the art and, thus, the rejection is overcome.

The Applicants submit that all claims in the application are in condition for allowance and such action is respectfully requested.

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The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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